

Appl. No. : 10/006,684  
Filed : November 8, 2001

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### REMARKS

Claims 1, 10 and 11 have been amended. Claim 12 has been canceled. Thus, Claims 1 and 3-11 remain presented for examination. Support for the amendments is found in the specification and claims as filed. Accordingly, no new matter has been added. Reconsideration of the application in view of the foregoing amendments and following comments is respectfully requested.

#### Rejection under 35 U.S.C. § 112, second paragraph

Claim 1 was rejected under 35 U.S.C. § 112, second paragraph as indefinite. The Examiner states that in claim 1, it is unclear if applicants are claiming antibodies directed toward the immune complex, or the antibody in the immune complex itself. The Examiner's interpretation that applicants are referring to the immune complex itself is correct, and the claim has been amended to clarify this point. The Examiner also states that the recitation of "optimal conditions" in claim 1 is ambiguous, and interprets this term as referring to healthy and normal. The Examiner's interpretation is again correct. Claim 1 has been amended to recite "healthy control patient", rather than "optimal conditions."

Claim 12 was rejected as indefinite since it was unclear if applicant intends to limit the first set of antibodies to a single antibody. Claim 12 has been canceled, thus rendering this rejection moot.

In regard to claims 10 and 11, the Examiner states that it is unclear if applications are limiting the set only to antibodies that bind to lupus peptides or arthritis peptides. These claims recite two particular embodiments in which the autoimmune disease is lupus and wherein the lupus antibodies bind to two particular peptides (Claim 10) and in which the autoimmune disease is lupus and wherein the lupus antibodies bind to one particular peptide (Claim 11).

The Examiner also requests clarification on whether the determination of the level of antibodies is performed for all antibodies in the first and second set, or only for a single antibody in each set. Claim 1 recites determining levels of a plurality of antibodies directed against a plurality of different antigens, wherein the first set of antibodies comprises myosin antibody, oxidized LDL antibody, heat shock protein-60 antibody, and  $\beta$ -2 glycoprotein-1 antibody. This means that antibody levels are determined for all of the antigens in the plurality of antigens,

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which include, but are not limited to, the specific antigens recited in the claims. This is also the case for the second set of antibodies.

In view of the foregoing amendments and comments, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

Rejection under 35 U.S.C. § 112, first paragraph (written description)

The Examiner rejected Claims 1-12 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner stated that although the specification provided support for the possibility of the presence of autoimmune disease and/or the presence of cardiovascular disease with autoimmune disease, it did not provide support for determining the presence of autoimmune disease and/or the presence of cardiovascular disease with autoimmune disease. Although Applicant does not agree with the position taken by the Examiner, Claim 1 as amended refers to only the possibility of these disorders.

Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejections under 35 U.S.C. § 112, first paragraph (written description).

Rejection under 35 U.S.C. § 112, first paragraph (enablement)

The Examiner alleges that the recitation of "immune complexes" in claim 1 is not enabled since immune complexes are only defined in the specification as when antibodies bind to antigens, and no definition was provided as to the identity of the antibodies. Claim 1 as amended recites that specific immune complexes, namely lupus peptide antibody immune complex and arthritis peptide immune complex, both of which are enabled by the specification as filed.

In addition, the Examiner contends that the specification, while being enabling for detecting immune complex disease, lupus and arthritis, or lack thereof, and detecting cardiovascular disease associated with myosin, oxidized LDL, and  $\beta$ -2 glycoprotein-1, or lack thereof, does not reasonably provide enablement for detecting all autoimmune and cardiovascular diseases, or optimal conditions. Although Applicant does not agree with the rejection, Claim 1 as amended recites the specific disorders acknowledged by the Examiner to be enabled.

Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejections under 35 U.S.C. § 112, first paragraph (enablement).

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In view of the foregoing amendments and comments, applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph (enablement).

CONCLUSION

In view of the foregoing amendments and comments, it is respectfully submitted that the present application is in condition for allowance. The undersigned has made a good faith effort to respond to all of the rejections set forth in the Office Action. If any matters remain that could be resolved by telephone, the Examiner is invited to contact the undersigned at the number provided below..

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410..

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: October 10, 2006

By: 

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